

## REMARKS

Entry of this Amendment and reconsideration of the subject application in view thereof are respectfully requested.

Claim 11 is pending in the application. The Examiner has rejected the pending claim under 35 U.S.C. § 102(b). The following remarks are considered by applicants to overcome the rejection raised by the Examiner. An early Notice of Allowance is, therefore, requested.

### Rejection Under 35 USC § 102

Claim 11 has been rejected under 35 U.S.C. § 102(b) as being anticipated by Lipshutz et al. 1999, Nature Genetics Supplement, 21:20-24 ("Lipshutz") in light of Smith et al., U.S. Patent 6,372,249 ("Smith"). Applicant respectfully traverses this rejection.

Claim 11 requires among other things an array of multiple oligonucleotides with different base sequences fixed onto known and separate positions on a support substrate . . . and said multiple oligonucleotides are classified according to their gene functions." In addition, the claim requires "the support substrate has fixation regions divided according to said classification, wherein the classification is (1) internal and external standard genes for proofreading, (2) stress-related genes related to heat shock protein and hormone genes that decreases under stress, (3) cytokine genes, (4) genes that induce cell death, (5) genes related to anti-inflammation and wound healing and genes related to cell growth inhibition, (6) transcription factor and signaling molecules related to immune response, (7) induction of cytokine, which causes cell injury, (8) transcription factor and signaling molecules related to growth inhibition, and (9) transcription factor and signaling molecules related to stress response.

A prior art reference anticipates a patent claim if the reference discloses, either expressly or inherently, all of the limitations of the claim. *Bristol-Myers Squibb v. Ben Venue*, 246 F.3d 1368 (Fed. Cir. 2001); *Schering Corporation v. Geneva Pharmaceuticals, Inc.*, 339 F.3d 1373 (Fed. Cir. 2003). Absence from the reference of any claimed element negates anticipation. *Kloster Speedsteel AB v. Crucible, Inc.*, 230 USPQ 81 (Fed. Cir. 1986). "Even if the claimed invention is disclosed in a printed publication, that disclosure will not suffice as prior art if it is not enabling." *In re Donohue*, 766 F.2d 531, 533 (Fed. Cir. 1985). See also, *Elan Pharmaceuticals, Inc. v. Mayo Foundation*, 2003 U.S. App. LEXIS 20195.

Applicant respectfully submits Lipshutz fails to teach each of the limitations of Claim 11. Specifically, for example, Lipshutz fails to teach that the support substrate has fixation

regions divided according to a classification based on gene functions and that classification is (1) to (9) as recited in Claim 11.

In support of the allegation that Lipshutz anticipates claim 11, the Examiner points to specific portions of Lipshutz (Figure 2; page 21, column 1, line 13 to page 22, column 2, line 29; and page 21, column 1, line 13 through column 2, line 16 of Lipshutz et al). Figure 2 shows an oligonucleotide array containing probe sets for about 40,000 human genes and ESTs. This Figure teaches or discloses nothing about, for example, a support substrate that has fixation regions divided according to a classification based on gene functions and that classification is (1) to (9) as recited in claim 11. Likewise, the remaining cited portions of the LipShutz reference also teach nothing about the substrate and the classification required by claim 11. Lipshutz's approach consists in the utilization of probe redundancy. A plurality of probe sequences are used for one target RNA so that they can hybridize to a plurality of sites of the target RNA. Also, as another utilization of probe redundancy, mismatched control probes (MM) are used which are different from one another in a single nucleotide at the middle of each probe from the completely mated probe (PM).

Applicant notes that Lipshutz detects a single gene by using a plurality of probe sequences redundantly for the purpose of measuring the expression level of the gene at a high reliability. In Lipshutz, the probe sequences are obtained from a plurality of sites within the same gene sequence, fixed and used for detection. Further, with respect to each probe sequence, MM sequences that are different only in a single nucleotide at the middle of each sequence are used for detection. Notwithstanding, Lipshutz does not teach or disclose a support substrate that has fixation regions divided according to a classification based on gene functions and that classification is (1) to (9) as recited in claim 11.

With regard to the Smith patent, the Examiner states that "Smith et al., [is] relied upon as a supporting document. Applicant notes that when a reference anticipates the claimed invention but is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to an extra reference. However, such evidence must make clear that the missing descriptive matter is necessarily (not possibly or probably) present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill in the art.

According to the Examiner, Smith "discloses known genes within the human genome that are related (classified) to the above described functions. See for example, Smith et al., Tables 5 and 10, Examples 5, 12 and 17 and column 33, line 31 through column 34, line 60."

The Smith patent describes the accumulated amount of SDI-1 RNA during cellular quiescence in Table 5; the induction of SDI-1 and growth arrest by various treatments such as radiation, active oxygen, UV, heat shock and chemical substances in Table 10 and Example 10; the induction of cell senescence by transfection with an antisense DNA vector in Example 5; and the association of SDI as an effector of p53 in Example 12. Such teachings, however, do not make clear that Lipshutz necessarily discloses the required features, for example, a support substrate that has fixation regions divided according to a classification based on gene functions and that classification is (1) to (9), and that it would be so recognized by persons of ordinary skill in the art.

As discussed above, the Examiner has not pointed to any text in Lipshutz in light of Smith, where it teaches each and every limitation of claim 11. It is Examiner's burden to show that each and every element is "necessarily present," not merely or possibly present in the Lipshutz reference. As such, the Examiner has not established a *prima facie* case of anticipation in support of the rejection of claim 11 based on Lipshutz in light of Smith. Therefore, in contrary to the Examiner's assertion, Lipshutz in light of Smith does not anticipate claim 11 as it does not teach or disclose each and every limitation in this claim.

Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §102 (b) are respectfully requested.

Conclusion

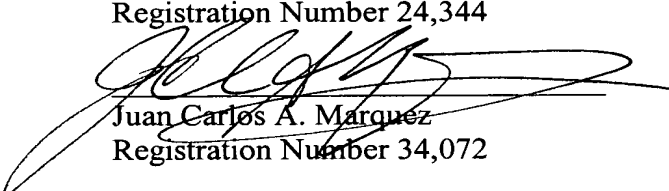
Applicant believes this response to be a full and complete response to the Office Action. Accordingly, favorable reconsideration in view of this response and allowance of the pending claim(s) are earnestly solicited.

If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the present application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,

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